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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/897,295 | 06/29/2001 | William J. Boyle | ACS-56001 (26361) | 1994 |
| 24201 | 7590 | 03/20/2006 | EXAMINER | |
| FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045 | | | MITCHELL, TEENA KAY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/897,295 | Applicant(s) BOYLE ET AL. | |
| | Examiner Teena Mitchell | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13, 20-26 and 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/3/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-13, 20-26, 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "...non-woven reinforcing member..." which was not previously presented in the originally filed specification constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is stretchable between the contracted position and expanded position. With respect to the limitation of the reinforcing member being non-woven, Hopkins does not teach a non-woven. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member be a non-woven, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the reinforcing member

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being a non-woven provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 3 with the reinforcing member being a non-woven

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of

Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). With respect to the non-woven note rejection of claim 3 above.

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Amplatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of

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the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase, which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the

expandable housing portion expands from the contracted position to the expanded position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 3 above.

With respect to claim 42, note rejection of claim 4 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used (Col. 4, lines 10-65).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6, 20, 21, 25, 41, 42, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Querns et.al. (5,944,691).

Querns discloses a restraining sheath (10) having an expandable housing portion (32, 34) adapted to receive and maintain the self-expanding medical device in a

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collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position and an expanded position (Figs. 2, 3), the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein: the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one non-woven reinforcing member (52) associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion (Figs. 2, 3).

With respect to claim 4, Querns discloses a plurality of non-woven reinforcing members (52) associated with the expandable housing portion to provide additional column strength to the housing portion.

With respect to claim 5, Querns discloses wherein the reinforcing members (52) extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material (Figs. 2, 3).

With respect to claim 6, Querns discloses the reinforcing members (52) are elongated bar-like members made from a material having high stiffness.

With respect to claim 20, Querns discloses the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section (54) to provide the elasticity needed to move the housing portion between the contracted position and expanded position (Figs. 2, 3).

With respect to claim 21, Querns discloses a plurality of low expansion sections (52) and a plurality of expansion members (54) disposed between low expansion sections (52).

With respect to claim 25, Querns discloses the expansion members (54) extend longitudinally along the length of the expandable housing portion.

With respect to claim 41, Querns discloses a restraining sheath (10) having an expandable housing portion (32, 34) adapted to expand between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a non-woven reinforcing member (52) associated with the expandable housing portion to maintain to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions (Figs. 2, 3).

With respect to claim 42, Querns discloses a plurality of non-woven reinforcing members (52) associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions (Figs. 2, 3).

With respect to claim 44, Querns discloses the reinforcing member (52) is an elongated bar-like member (52) made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.

With respect to claim 51, Querns discloses wherein the reinforcing member (52) helps to bias the expandable housing portion in the contracted position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Querns (5,944,691).

With respect to claim 7, Querns does not specifically disclose the elastic material selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability

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for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Querns to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 10-13, note rejection of claim 7 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

Claims 9, 22, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Querns (5,944,691) in view of Hopkins (6,544,279).

The difference between Querns and claim 9 is the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to modify the reinforcing members of Querns with a material having a high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claims 22 and 47, note rejection of claim 9 above.

Response to Arguments


Applicant's arguments filed 1/03/06 have been fully considered but they are not persuasive. Applicant argues that the Hopkins/Amplatz is not expandable, however, applicant is referred to the comments in the rejection above with respect to expandable (note claim 3 above; also note Col. 4, lines 10-65 which teach shape memory alloy such as NiTi which are very elastic-they are said to be "superelastic" or "pseudoelastic"). Applicant also adds the limitation of "non-woven" to the claims, while applicant list materials in the specification for the reinforcing member, which may be non-woven, there is nothing in the specification which states the reinforcing members are non-woven, therefore this limitation to the claims is considered new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Teena Mitchell
Primary Examiner
Art Unit 3743
March 14, 2006


TKM